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APPENDICES

APPENDIX A

Physicochemical Properties of Plasticizers

1. Sorbitol

1.1 Chemical name

D-Glucitol, Sorbitolum

1.2 Molecular formulation

$C_6H_{14}O_6$

1.3 Molecular weight

182.17

1.4 Appearance

White granules, flakes, or microcrystalline powder, odourless.

1.5 Solubility

Soluble in 0.5 part of water; sparingly soluble in ethanol; practically insoluble in chloroform and in ether.

1.6. Stability and storage condition

It is slightly hygroscopic. Sorbitol shall be kept in tightly closed containers.

1.7 Use and Safety

Sorbitol is a polyhydric alcohol with half the sweetening power of sucrose. It has been employed as a 30% solution as an alternative to glucose in parenteral nutrition but its use is not recommended because of the risk of lactic acidosis. Sorbitol also acts as a bulk sweetening agent. It is used in limited quantities either as a sweetening agent or as a source of carbohydrate in diabetic food products. It is also used as a sweetening agent instead of sucrose in many sugar-free oral liquid preparations and in sugar-free preparations for the prevention of dental caries. Sorbitol also has humectant and stabilizing properties and is used in various pharmaceutical and cosmetic products including toothpaste. Excessive ingestion of sorbitol may cause flatulence, abdominal distension and diarrhea.

2. Polyethylene Glycol 400 (PEG 400)

2.1 Chemical name

α-hydro-ω-hydroxypoly-(oxy-1,2-ethanediyl)glycol

2.2 Molecular formulation

$HOCH_2(CH_2OCH_2)_n\ CH_2OH$

2.3 Molecular weight

380-420

2.4 Appearance

Clear, colorless or slightly yellowish, viscous liquid having hygroscopic properties. The odor is slight but characteristic, and the taste is bitter and slightly burning.

2.5 Solubility

Soluble in water, alcohols, glycols, acetone and benzene.

2.6 Stability and storage condition

It is chemically stable in air and in solution. PEG 400 do not support microbial growth nor become rancid. Oxidation may occur if PEG 400 is exposed for long periods to temperatures exceeding 50 °C. This material should be stored in well-closed container.

2.7 Use and Safety

PEG 400 can be used to be a solvent, solubilizer, suspending agent, emulsion stabilizer and lubricant. It is widely used as plasticizer in conjunction with film-former. It is useful as plasticizers in micro-encapsulated products to avoid rupture of the coating film when microcapsules are compressed into tablet.

3. Polyethylene Glycol 6000 (PEG 6000)

3.1 Chemical name

α-hydro-ω-hydroxypoly-(oxy-1,2-ethanediyl)glycol

3.2 Molecular formulation

$HOCH_2(CH_2OCH_2)_m\ CH_2OH$

3.3 Molecular weight

6000

3.4 Appearance

White or off-white in color, and range in consistency from pastes to waxy flasks.

3.5 Solubility

Soluble in acetone, dichloromethane, ethanol and methanol; it is slightly soluble in aliphatic hydrocarbons and ether but insoluble in fats, fixed oils and mineral oil.

3.6 Stability and storage condition

It is chemically stable in air and in solution. PEG 6000 can be sterilized by autoclaving filtration or gamma irradiation and dry heat at 150 °C for one hour may induce oxidation, darkling and the formation of acidic degradation products. PEG 6000 should be stored in well-closed containers in a cool, dry place.

3.7 Use and Safety

PEG 6000 can enhance the effectiveness of tablet binder and impart plasticity to granules, solubilizer, suspending agent, emulsion stabilizer and lubricant.

4. Hydroxypropyl Methylcellulose (HPMC)

4.1 Chemical name

Cellulose, 2-Hydroxypropyl methyl ether

4.2 Molecular formulation

$C_8H_{15}O_6$-$(C_{10}H_{18}O_6)_n$- $C_8H_{15}O_5$

4.3 Molecular weight

10,000-1,500,000

4.4 Appearance

White, yellowish white or grayish white powder or granules, odorless and tasteless.

4.5 Solubility

Soluble in cold water, forming a viscous colloidal solution, insoluble in absolute ethanol, acetone, ether, toluene, chloroform, but soluble in mixtures of methyl alcohol and methylene chloride.

4.6 Stability and storage condition

Hypromellose shall be kept in well-closed containers.

4.7 Use and Safety

Hydroxypropyl methylcellulose is widely used as an excipient in oral or topical pharmaceutical formulations. It is also extensively used in cosmetics and food products. Hydroxypropyl methylcellulose is generally regarded as a nontoxic and nonirritant material although excessive oral comsumption may have a laxative effect.

APPENDIX B

1. Peak area of Triamcinolone acetonide and PG film base per surface area (cm^2) through cellulose acetate membrane

Formula	Time (hr)	Peak area ($x10^3$)			Mean	SD
		1	2	3		
1TPG	0	0	0	0	0	0
	0.08	10.201	21.026	17.522	16.250	5.524
	0.17	31.546	38.883	30.136	33.522	4.696
	0.25	39.888	55.780	43.802	46.490	8.280
	0.33	66.718	68.571	53.171	62.820	8.407
	0.5	77.710	76.397	61.426	71.844	9.046
	0.75	86.174	82.210	74.467	80.950	5.954
	1	94.274	90.061	79.579	87.971	7.567
	2	94.274	90.061	79.579	87.971	7.567
	3	94.274	90.061	79.579	87.971	7.567
S30PG	0	0	0	0	0	0
	0.08	11.768	8.202	7.932	9.301	2.141
	0.17	11.768	8.202	7.932	9.301	2.141
	0.25	21.943	16.586	20.045	19.525	2.716
	0.33	40.532	34.113	35.478	36.708	3.382
	0.5	63.251	45.637	35.478	48.122	14.052
	0.75	77.220	45.637	35.478	52.778	21.768
	1	77.220	45.637	35.478	52.778	21.768
	2	85.891	63.637	51.318	66.949	17.523
	3	101.011	63.637	71.098	78.582	19.779

1.1. Drug release (mg) of Triamcinolone acetonide per surface area (cm^2) through cellulose acetate membrane

Time (hr)	Peak area ($x10^3$)	Drug concentration (mg/ml)	Drug release (mg)
0	0	0	0
0.08	16.250	0.00000054	0.0000072
0.17	33.522	0.00000112	0.0000148
0.25	46.490	0.00000155	0.0000205
0.33	62.820	0.00000209	0.0000276
0.5	71.844	0.00000240	0.0000316
0.75	80.950	0.00000270	0.0000356
1	87.971	0.00000293	0.0000387
2	87.971	0.00000293	0.0000387
3	87.971	0.00000293	0.0000387

2. Optical Density (OD) of Miconazole nitrate and PG film base per surface area (cm^2) through cellulose acetate membrane

Formula	Time (hr)	OD 232 nm			Mean	SD
		1	2	3		
1MPG	0	0	0	0	0	0
	0.25	0.0860	0.0650	0.0480	0.0663	0.0190
	0.50	0.1140	0.0891	0.0760	0.0930	0.0193
	0.75	0.1730	0.1347	0.1030	0.1369	0.0351
	1	0.1940	0.1519	0.1200	0.1553	0.0371
	2	0.2510	0.1978	0.1570	0.2019	0.0471
	3	0.3160	0.2471	0.1730	0.2454	0.0715
	4	0.3450	0.2699	0.1930	0.2693	0.0760
	8	0.4110	0.3240	0.2600	0.3317	0.0758
	20	0.4970	0.3957	0.3360	0.4096	0.0814
	22	0.5280	0.4216	0.3600	0.4365	0.0850
	24	0.5230	0.4174	0.3560	0.4321	0.0845
S30PG	0	0	0	0	0	0
	0.25	0.0650	0.0583	0.0540	0.0591	0.0055
	0.50	0.0850	0.0775	0.0770	0.0798	0.0045
	0.75	0.1050	0.0970	0.1020	0.1013	0.0040
	1	0.1200	0.1124	0.1280	0.1201	0.0078
	2	0.1440	0.1343	0.1320	0.1368	0.0064
	3	0.1800	0.1659	0.1410	0.1623	0.0197
	4	0.1900	0.1750	0.1510	0.1720	0.0197
	8	0.2030	0.1866	0.1620	0.1839	0.0206
	20	0.2220	0.2050	0.2030	0.2100	0.0104
	22	0.2220	0.2050	0.2190	0.2153	0.0091
	24	0.2220	0.2050	0.2200	0.2157	0.0093

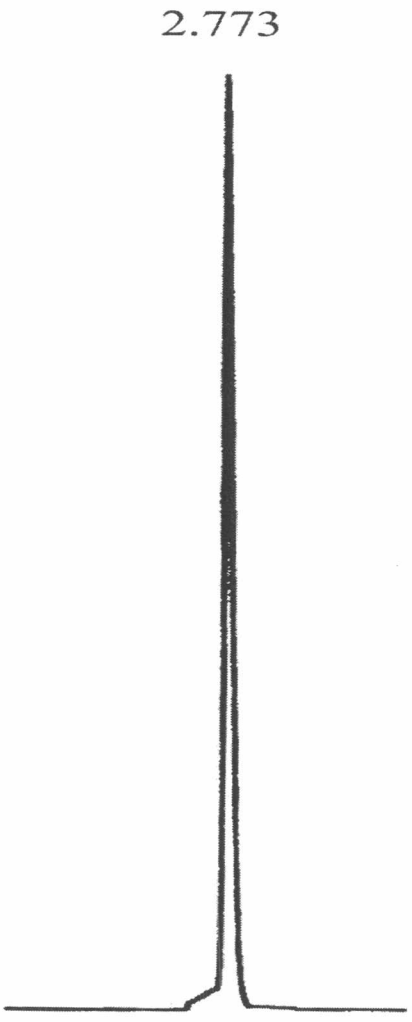
2.1. Drug release (mg) of Miconazole nitrate per surface area (cm^2) through cellulose acetate membrane

Time (hr)	OD 232 nm	Drug concentration (mg/ml)	Drug release (mg)
0	0	0	0
0.25	0.0663	0.0032	0.0438
0.50	0.0930	0.0045	0.0615
0.75	0.1369	0.0067	0.0905
1	0.1553	0.0076	0.1027
2	0.2019	0.0099	0.1335
3	0.2454	0.0121	0.1623
4	0.2693	0.0132	0.1781
8	0.3317	0.0163	0.2193
20	0.4096	0.0202	0.2709
22	0.4365	0.0215	0.2887
24	0.4321	0.0213	0.2858

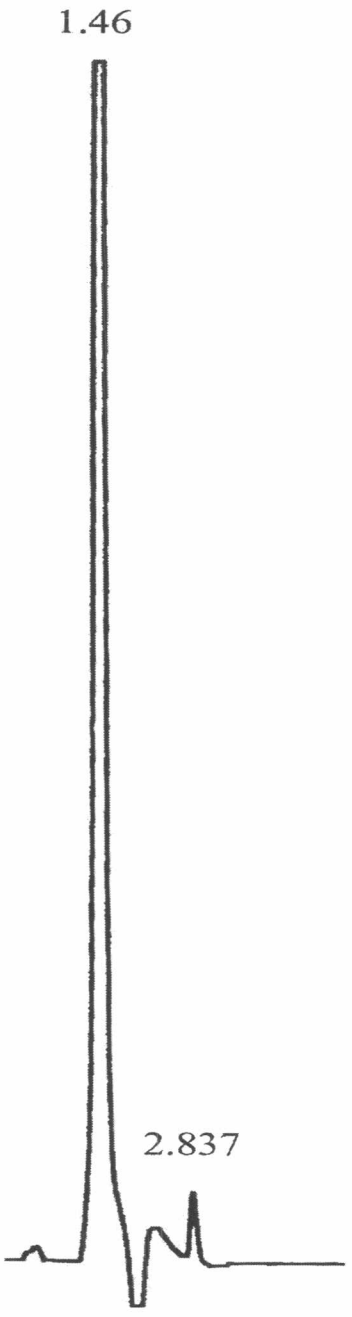
APPENDIX C

HPLC chromatograms of (a) Standard Triamcinolone Acetonide, (b) Triamcinolone Acetonide Film, (c) Polysaccharide Gel (PG) Film

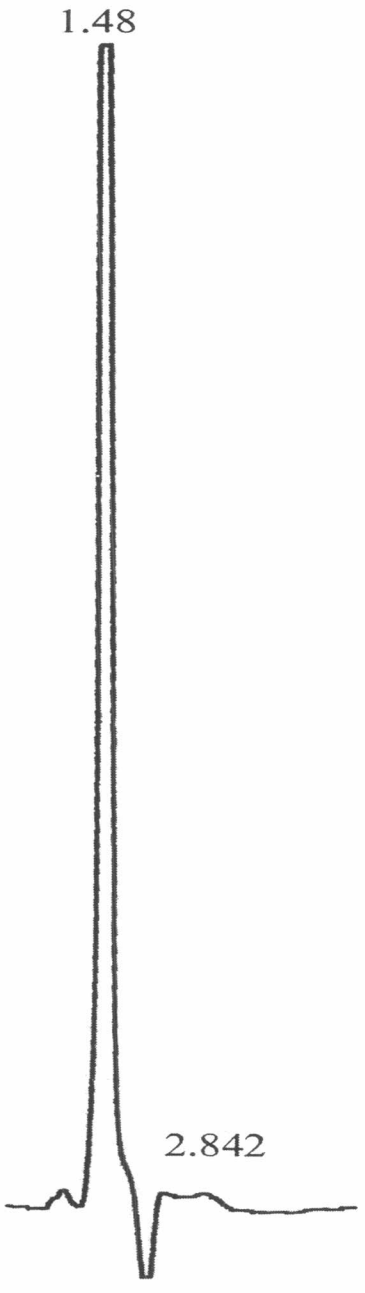
(a) Standard Triamcinolone Acetonide



(b) Triamcinolone Acetonide Film



(c) Polysaccharide Gel (PG) Film



APPENDIX D

The thickness of PG films in various formulation

Formula	Thickness (μm)					Mean	SD
	1	2	3	4	5		
PG	0.035	0.040	0.025	0.030	0.030	0.032	0.006
S10PG	0.030	0.035	0.025	0.040	0.045	0.035	0.008
S20PG	0.030	0.045	0.040	0.050	0.040	0.041	0.007
S30PG	0.035	0.035	0.040	0.055	0.050	0.043	0.009
S40PG	0.040	0.045	0.045	0.055	0.055	0.048	0.007
S50PG	0.065	0.050	0.045	0.055	0.050	0.053	0.008
P4/30PG	0.055	0.035	0.040	0.045	0.055	0.046	0.009
P6/1PG	0.040	0.040	0.045	0.050	0.035	0.042	0.006
P6/1.5PG	0.040	0.050	0.045	0.035	0.035	0.041	0.007
P6/2PG	0.035	0.035	0.040	0.045	0.035	0.038	0.004
HPMC	0.045	0.055	0.040	0.035	0.050	0.045	0.008
H1PG	0.045	0.030	0.035	0.030	0.040	0.036	0.007
H3PG	0.030	0.035	0.040	0.035	0.045	0.037	0.006
H5PG	0.035	0.040	0.045	0.040	0.045	0.041	0.004
H20PG	0.035	0.045	0.040	0.045	0.050	0.043	0.006
1TPG	0.055	0.065	0.060	0.070	0.065	0.063	0.006
1MPG	0.045	0.050	0.065	0.055	0.060	0.055	0.008
3S30PG	0.060	0.075	0.080	0.070	0.065	0.070	0.008
TPG	0.065	0.090	0.085	0.075	0.065	0.076	0.011
MPG	0.075	0.090	0.095	0.085	0.075	0.084	0.009

APPENDIX E

The moisture sorption of PG films and HPMC film at 75% RH

Formula	% Moisture sorption			Mean	SD
	1	2	3		
S30PG	21.60	17.52	19.29	19.47	2.05
3S30PG	19.28	18.63	17.83	18.58	0.73
HPMC	9.97	8.32	8.06	8.78	1.03

APPENDIX F

The Questionnaire of Sensory analysis test

<u>แบบสอบถาม</u>

เพศ ☐ ชาย ☐ หญิง

อายุ .....ปี

เคยเป็นแผลร้อนในในปากหรือไม่ ☐ เคย ☐ ไม่เคย

ความถี่ของการเป็นแผลในปาก ☐ บ่อยๆ

☐ 1-2เดือน/ครั้ง

☐ 3-6เดือน/ครั้ง

☐ 6เดือน-1ปี/ครั้ง

☐ 1-2ปี/ครั้ง

วิธีการรักษาที่เคยใช้ 1 ☐ ปล่อยให้หายเอง 2 ☐ ใช้ผลิตภัณฑ์เจล

3 ☐ ใช้ผลิตภัณฑ์ฟิล์ม 4 ☐ ใช้น้ำยาบ้วนปาก

ความรู้สึกเมื่อแปะแผ่นฟิล์มทุเรียน

คำถาม	**ความพอใจในผลิตภัณฑ์**			
	0 ไม่มี	**1** น้อย	**2** ปานกลาง	**3** มาก
ความพอใจในรสชาติ				
ความสะดวกในการแปะในช่องปาก				
การติดแน่นเมื่อแปะในช่องปาก				
ความรู้สึกไม่ระคายเคืองเมื่อแปะในช่องปาก				
ไม่มีสิ่งที่คงเหลืออยู่ในปาก (residue)				
ความรู้สึกไม่รำคาญเมื่อแปะในช่องปาก				
ความพึงพอใจในผลิตภัณฑ์ก่อนการใช้				
ความพึงพอใจในผลิตภัณฑ์ภายหลังการใช้				

- หากมีผลิตภัณฑ์รูปแบบนี้ในท้องตลาดจะซื้อหรือไม่ ☐ ซื้อ ☐ ไม่ซื้อ

ข้อเสนอแนะเพิ่มเติม : .....

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VITA

Miss Tanaporn Tachatawepisarn was born on September 23, 1979 in Bangkok, Thailand. She graduated Diploma in Analytical Chemistry in 1999 from Institute of Analytical Chemistry Training, Chulalongkorn University, Thailand. Bechelor's Degree of Science in 2001 from Department of Biochemistry, Faculty of Science, Chulalongkorn University.